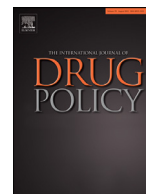




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Research Paper

A stakeholder-driven framework for measuring potential change in the health risks of people who inject drugs (PWID) during the COVID-19 pandemic



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ABSTRACT

Background: People who inject drugs (PWID) have likely borne disproportionate health consequences of the COVID-19 pandemic. PWID experienced both interruptions and changes to drug supply and delivery modes of harm reduction, treatment, and other medical services, leading to potentially increased risks for HIV, hepatitis C virus (HCV), and overdose. Given surveillance and research disruptions, proximal, indirect indicators of infectious diseases and overdose should be developed for timely measurement of health effects of the pandemic on PWID.

Methods: We used group concept mapping and a systems thinking approach to produce an expert stakeholder-generated, multi-level framework for monitoring changes in PWID health outcomes potentially attributable to COVID-19 in the U.S. This socio-ecological measurement framework elucidates proximal and distal contributors to infectious disease and overdose outcomes, many of which can be measured using existing data sources.

Results: The framework includes multi-level components including policy considerations, drug supply/distribution systems, the service delivery landscape, network factors, and individual characteristics such as mental and general health status and service utilization. These components are generally mediated by substance use and sexual behavioral factors to cause changes in incidence of HIV, HCV, sexually transmitted infections, wound/skin infections, and overdose.

Conclusion: This measurement framework is intended to increase the quality and timeliness of research on the impacts of COVID-19 in the context of the current pandemic and future crises. Next steps include a ranking process to narrow the drivers of change in health risks to a concise set of indicators that adequately represent framework components, can be written as measurable indicators, and are quantifiable using existing data sources, as well as a publicly available web-based platform for summary data contributions.

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Introduction

The COVID-19 pandemic has affected nearly every aspect of human health, but as with most diseases, its impacts are not distributed equally across populations. Populations at higher risk, such as those who are structurally marginalized due to race/ethnicity, socio-economic status, or class, have borne disproportionate consequences of the pandemic (Magesh et al., 2021; Munoz-Price et al., 2020; Zelner et al., 2021). People who inject drugs (PWID) may be affected by COVID-19 in myriad ways due at least in part to pre-existing socio-economic disadvantage and marginalization combined with limited access to services and stigmatization (Iversen et al., 2020; Saloner et al., 2022; Vasylyeva et al., 2020). As a population, PWID have high levels of mental health conditions, chronic health conditions, unemployment, poverty, incarceration, and unstable housing (Allen et al., 2019; Hershow et al., 2021; Marel et al., 2021; Stone et al., 2018; Vasylyeva et al., 2020). Because non-medical injection drug use (IDU) is a criminalized and stigmatized behavior in the U.S. and some other countries, PWID tend to delay or forgo accessing health care and social services, which exacerbates vulnerability to health risks including infectious diseases and drug overdose (Paquette et al., 2018).

In addition to high risk for COVID-19 infection and related outcomes including hospitalization and death (Allen et al., 2021; Atalla et al., 2021; Baillargeon et al., 2021; Centers for Disease Control and Prevention, 2021a; Strathdee et al., 2021; Velasquez Garcia et al., 2021; Wang et al., 2021), other health risks among PWID have likely increased in the pandemic era (Melamed et al., 2020; Walters et al., 2020). Health effects may include increased incidence and diminished management of HIV, hepatitis C virus (HCV), sexually transmitted infections (STI), and skin and soft tissue infections, as well as fatal and non-fatal overdose (Gleason et al., 2021; Hoenigl et al., 2021; Mellis et al., 2021; Mistler et al., 2021; National Center for Health Statistics, 2021; Stanford et al., 2021; Strathdee, 2021; Walters et al., 2020; Zang et al., 2021; Zhang et al., 2021). The extent to which COVID-19 has exacerbated burden of infectious diseases among PWID is still unknown, but HIV outbreak data indicate the pandemic has intensified transmission and hampered control efforts (Taylor et al., 2021). Similarly, recent data from the U.S. indicate drug overdose deaths increased by 28.5% during April, 2020 – April, 2021 (National Center for Health Statistics, 2021). History suggests similar increases in infectious diseases will be observed. Infectious disease outbreaks among PWID during the past decade have been precipitated by economic downturns, increases in homelessness, and reductions in preventive and harm reduction services – all features of the current pandemic (Alpren et al., 2020; Bartholomew et al., 2020; Centers for Disease Control and Prevention, 2021e; Des Jarlais et al., 2020; Kaufman et al., 2021; Lyss et al., 2020; Mackey & Strathdee, 2015; Oster et al., 2021; Strathdee et al., 2021).

Measuring change in PWID health outcomes during the COVID-19 pandemic will be challenging, particularly in the short-term, and creative approaches will be needed to identify health needs and areas for intervention. The U.S. has limited surveillance for measuring PWID health outcomes (Strathdee et al., 2021). The National HIV Behavioral Surveillance (NBHS) system, which is limited to urban settings and is the only national surveillance system for PWID health, is conducted only every three years, most recently in 2018 (Handanagic et al., 2021), with the next PWID cycle being delayed until 2022 due to the pandemic (Centers for Disease Control and Prevention, 2021d). Other infectious disease surveillance systems rely on case reports from testing and screening programs, which have also been disrupted as many programs, such as syringe service programs, suspended testing operations at least temporarily during the pandemic (Des Jarlais et al., 2020) and health department staff that typically manage case reporting for surveillance were largely detailed to COVID-19 work (Weber et al., 2021). Additionally, HIV and HCV testing were interrupted at many sites due to limited personal protection equipment and the need for social distancing (Mistler et al., 2021; Zang et al., 2021). The pandemic also impacted

non-fatal overdose syndromic surveillance, typically conducted in the context of emergency room visits, which declined due to concerns about acquiring COVID-19 (Czeisler et al., 2020). For timely measurement of the health effects of the pandemic on PWID and to facilitate evaluations of interventions, more proximal, indirect indicators of infectious diseases, overdose, and adverse mental health outcomes should be considered.

Scientific collaboration and data-sharing have been a positive hallmark of the pandemic, allowing diagnostic tools and vaccines for SARS-CoV-2 to be developed in record time (Strathdee et al., 2021). Social scientists have an opportunity to rapidly collaborate to improve pandemic-related health outcomes for PWID and other vulnerable populations. This will require new partnerships and strengthening of existing alliances, as well as an openness to freely sharing ideas, experiences, and data prior to peer-reviewed publication.

In this paper, we propose an expert stakeholder-generated, multi-level framework for monitoring changes in PWID health outcomes potentially attributable to COVID-19 in the U.S. Three intended framework applications guided its development. First, we aimed to elucidate proximal contributors to infectious disease and overdose outcomes that can be measured using existing data sources apart from those delayed by surveillance challenges. Second, we aimed to increase investments in PWID health and implementation research efforts that integrate complex and multi-faceted causes of infectious disease transmission and overdose. Last, we aimed to provide a conceptual framework of factors and processes to consider when assessing programmatic effectiveness or changes in the population-level health of PWID in the context of a pandemic or other public health crises.

Methods

During March 2021, we invited 105 expert stakeholders working in the field of PWID health research, policy, and programs to participate in a series of group concept mapping exercises and systems-focused discussions (Hassmiller Lich et al., 2017; McGill et al., 2021), eliciting and organizing potential changes in PWID health during COVID-19. Of invited stakeholders, 53 attended a session; each invitee was asked to join only one session. All sessions were also joined by core team members (H.B., D.C.D.J., E.R., C.A., A.C.). Stakeholders represented academic institutions, federal, state, and local government agencies, harm reduction/clinical services, and policy-focused organizations. Due to the U.S. focus of this work, most stakeholders were U.S.-based, but we also included stakeholders from the U.K., Canada, Europe, and Australia due to rich expertise in PWID health in these areas. Academic stakeholders were identified through the professional networks of the core team and by searching Grants.gov, NIH RePORTER, and PubMed for investigators currently conducting research in PWID health. Government, service-providing, and policy-focused organizational representatives were identified through our networks, primary Centers for Disease Control and Prevention (CDC) and National Institutes of Health (NIH) contacts, and by referral from other stakeholders. All invited stakeholders had the opportunity to recommend additional experts, who were in turn added to the invitee list.

The core team facilitated a series of 5, 90-minute mapping and discussion sessions with stakeholder groups (Fig. 1).

In these sessions, we first presented stakeholders with a “skeleton” framework for measuring pandemic-related changes in health risks among PWID (Fig. 2). We asked them to elaborate on how this framework might be expanded to holistically represent changes in risk for HIV infection, HCV infection, and overdose during the pandemic (i.e., other major categories of risk or protection in which they 1) were observing change through emergent data and/or 2) had a theoretical basis for believing COVID-19 was contributing to changes). We then asked stakeholders to identify and map unique factors that that fell into each of those larger categories and to provide additional detail on inter-relationships across the categories, e.g., stay-at-home policies decreas-

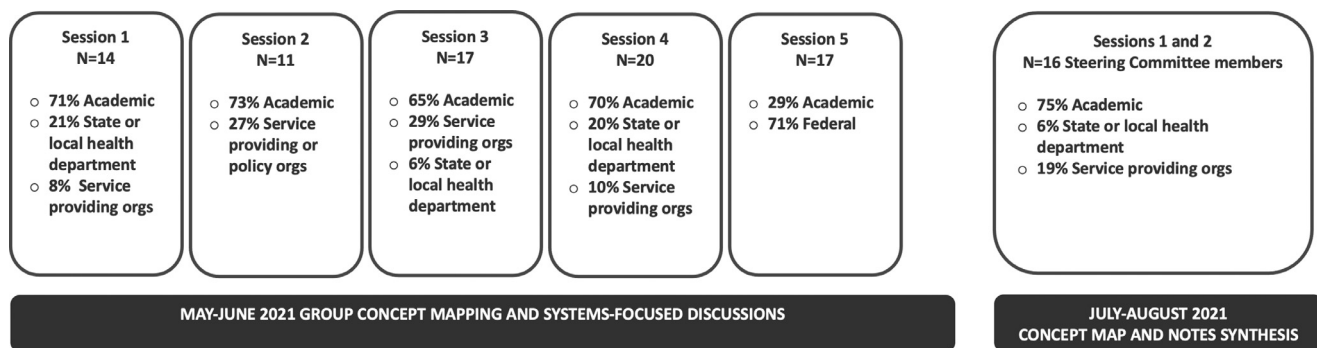


Fig. 1. Stakeholder discussion timeline.

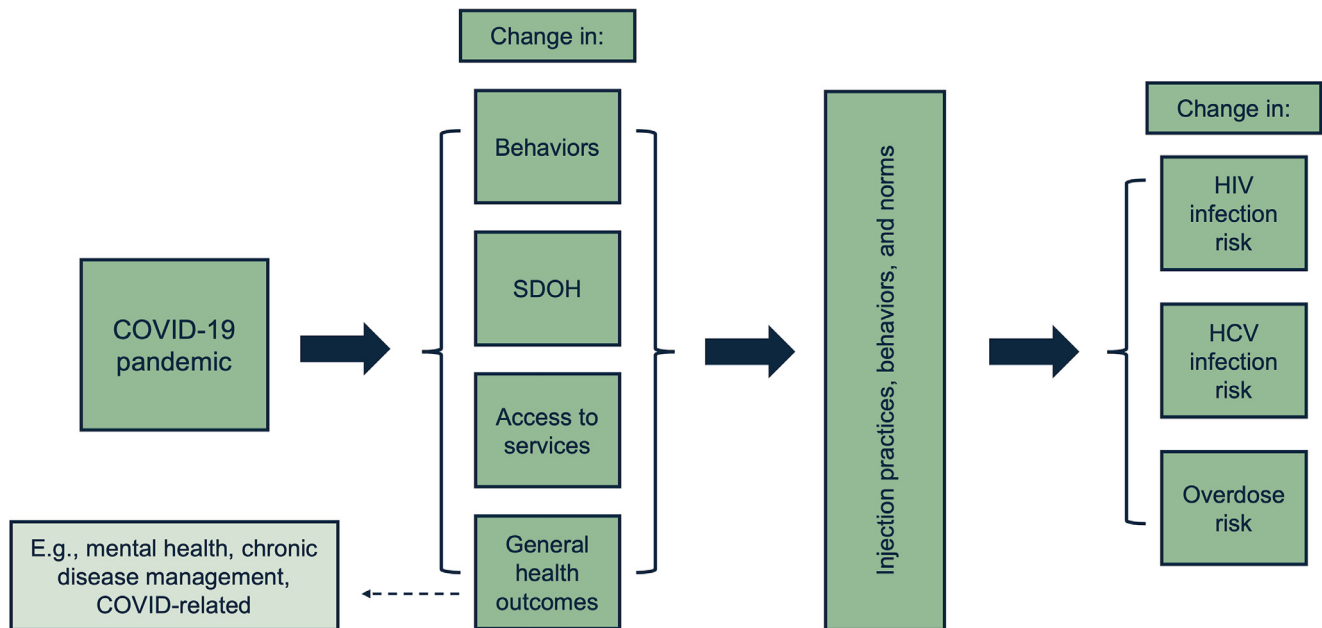


Fig. 2. ‘Skeleton’ framework for understanding change in PWID health risks during the COVID-19 pandemic.

ing opportunities for social connectedness among PWID. As these factors were mapped, we solicited potential data sources that could facilitate measurement of identified constructs. We used the Mural Online Collaboration platform (Mural, 2021) to graphically facilitate and capture discussion sessions and to make real-time notes of all contributing factors mentioned in an illustration of each ‘skeleton framework’ component. After each discussion, we sent meeting notes to participants, in text and Mural illustration formats, for additions or corrections.

Following these sessions, we invited participants to serve on a steering committee to assist the core team in further synthesizing the graphical diagrams resulting from the five sessions, and operationalizing the final measurement framework. Steering committee members, with representation from each organizational type, iterated on notes and graphics from all five stakeholder discussions and expanded the skeleton framework into a more comprehensive framework (Fig. 3). The steering committee also reviewed and finalized factors potentially contributing to change in PWID health during the pandemic for each component of the expanded framework.

SDOH: social determinants of health; HIV: human immunodeficiency virus; HCV: hepatitis C virus.

Findings

Findings are presented in two phases: 1) development and 2) description of the framework.

Framework development

Steering committee members requested substantial modifications to the skeleton framework in service of our primary aims. To facilitate this expansion, steering committee members consulted a broad range of framework orientations, including Bronfenbrenner’s ecological model (Bronfenbrenner, 2004; Cowan et al., 2021; Guo et al., 2021; Henderson et al., 2020) and the risk-environment model (Collins et al., 2019; Rhodes, 2002). Because no framework as written sufficiently accommodated abrupt changes to the mezzo-environment, particularly the drug supply system and service delivery, stakeholders opted for a hybrid approach, using elements from both the ecological and risk-environment models, to illustrate the complex, multi-level, and dynamic nature of pandemic-related changes, and the proximal and distal effects they may have on PWID health outcomes through various pathways.

A list of resulting framework modifications is presented in Table 1.

Framework description

The measurement framework following post-steering committee expansion and revisions is shown as Fig. 3. All components of the framework are described below, and Table 2 details the full list of potential pandemic-related changes in PWID health risks that were identified by stakeholders, by framework component. The framework is timebound

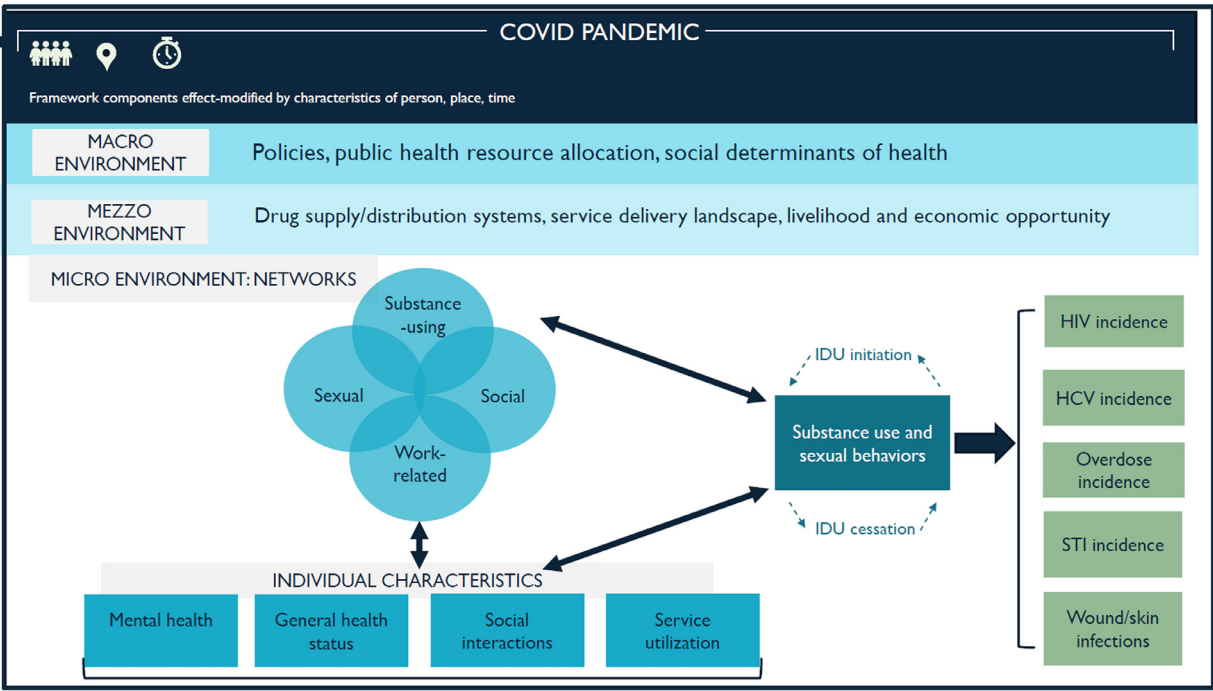


Fig. 3. Framework for measuring change in PWID health risks during the COVID-19 pandemic.

Table 1 Framework revisions informed by steering committee.	
Requested framework modifications	Incorporated modifications
Reflect ecological scale of potential health effects visually and in text	Added Macro-, Mezzo-, and Micro-environment levels and reorganized sub-components by these levels
Add or parse indicator categories particularly sensitive to COVID-19 pandemic	Moved Macro- and Mezzo-environment levels from far left to top of figure to convey their ubiquitous effect
	Separated “Policies,” “Public health resource allocation,” “Drug supply/distribution systems,” and “Economic opportunity” from more general “Social Determinants of Health”
	Separated “Mental Health” from “General health”
	Changed “Access to Services” to “Service Utilization”
	Added “STI incidence” and “Wound/skin infections” as health outcomes
Represent PWID health outcomes more comprehensively	
Acknowledge service access is a function of service offerings as well as usage	Separated service delivery landscape (mezzo level) from service utilization (individual level)
Differentiate network behavior from individual behavior	Added “Micro-environment Networks” category level and subsequent network types: “Substance-using,” “Sexual,” “Work-related,” and “Social”
	Placed network indicator circles in Venn diagram to indicate potential for overlapping among network communities
Account for injection initiation and cessation	Added entry and exit loops to demonstrate transitions between injecting and not injecting drugs, i.e., allow people to leave or enter the framework
Add arrows to show bidirectionality and direct and indirect pathways between components	Added arrow from “Micro-environment Network” to “Sexual and Substance-using behaviors” to show potentially direct pathway between these components
	Changed arrow between “Micro-environment Networks” and “Sexual and Substance-using behaviors” to two-headed arrow to show interaction/feedback between these levels
	Placed two-headed arrow between “Micro-environment Networks” and “Individual Characteristics”

by the period during which PWID health risks may be affected by the COVID-19 pandemic (Baker et al., 2021; Phillips, 2021).

Framework components

Table 2 shows indicators of potential change in PWID health during the COVID-19 pandemic. These are organized by socio-ecological level and sub-categories where applicable. These are not intended to be interpreted as measurement indicators that can be operationalized to determine the magnitude of change expected during a specific time. Rather, this list represents areas of potential change that should be considered when measuring change in PWID health outcomes before and after the COVID-19 pandemic began.

Macro-environment

The macro-environment comprises structural factors and processes (power dynamics, distributional forces, norms, etc.) that exert high-

level influence on PWID health risks during the COVID-19 pandemic (Diez Roux, 2012; McGowan et al., 2017). In this framework, macro-level factors and processes are divided into three categories: policies, public health resource allocation, and social determinants of health.

Policy changes include, for example, change in harm reduction-related policies such as syringe distribution laws, as well as pandemic-related policies such as stay-at-home orders. Public health resource allocation represents changes in financial infrastructure and personnel working in PWID health during the pandemic. These include shifts in health department funding and staff toward COVID-19 from other public health priority areas, as well as changes in federal and state-level programmatic funding for PWID-focused service-providing organizations. Notably, these shifts may be beneficial or harmful in terms of PWID health risks. One example of a beneficial shift is the recent announcement (April, 2021) from the CDC and the Substance Abuse and Mental Health Services Administration (SAMHSA) that, due to substantial in-

Table 2

Indicators of potential change in PWID health risks during the COVID-19 pandemic identified by stakeholders, by framework component.

MACRO-ENVIRONMENT***Changes in policies*****Health-related policies**

Syringe and equipment distribution policies and laws

Programmatic guidelines for HIV/HCV screening (e.g., frequency)

Programmatic guidelines for HIV/HCV/substance use disorder treatment (e.g., timing for initiation)

Pandemic-related policies

COVID-related policies impacting SSP supply distribution (e.g., deeming “essential services”)

Stay-at-home orders

Mask mandates

Specific protections and guidelines for vulnerable populations (sex workers, people experiencing homelessness)

Stimulus funding policies

Changes in public resource allocation

Shifts in health department funding toward COVID-19 from other areas

Shifts in programmatic funding for service providing organizations from federal and state budgets

Shifts in jail and prison budgets

Changes in social determinants of health**Law enforcement and incarceration**

Disruption of encampments by law enforcement

Drug-related arrests

Harassment from law enforcement

De-incarceration to reduce COVID spread

Structural Racism

Shifts in attitudes and experiences of structural racism during racial reckoning (both exacerbated and attenuated)

Racially motivated policing practices

MEZZO-ENVIRONMENT***Changes in drug supply and distribution systems***

Changes to adulterants (cuts) used in street drugs

Changes in pricing of prescription and illicit drugs

Contamination of drug supply

Shifting sources for drug procurement

Changes in service delivery landscape**HIV and HCV screening and testing**

Distribution of testing supplies to service delivery organizations

Shifts to tele-testing and screening

Shifts to mobile (e.g., curbside) screening and testing, other delivery modalities

Diagnostic technologies

Provision of treatment and/or medication

Referrals to HIV/HCV/substance use disorder care and treatment

Availability of HIV/HCV/substance use disorder care and treatment

Shift to remote or tele-treatment for HIV/HCV/substance use disorder, other delivery modalities

Provision of detoxification services

Prescription opioid prescribing and dispensing practices

Naloxone and injectable Naltrexone dispensing practices

Methadone and buprenorphine dispensing practices

Other programs and services

Availability of HIV/HCV/substance use disorder care navigation and coordination

Shift to mail-based, vending machine, touchless, or other modalities for harm reduction supplies including syringes

Provision of pipes

Secondary exchange and/or peer delivery of supplies

Availability of safe syringe disposal

Provision of prison/jail throughcare services

Provision of in-person peer support groups or informal educational/support conversations with SSP staff

Provision of 12-step meetings

Provision of primary care services

Provision of mental health care services

Provision of wound care services

Operations and staffing for service providing organizations (especially for harm reduction organizations)

Availability of physical space for service delivery

Closing, pausing of operations, operating hours

Fixed versus satellite/remote sites

Coverage areas and characteristics of clients

Management of clients across integrated services

Staff stress and morale

Availability of supply of syringes and other equipment for clients

Availability of staff (diversions, resignations, safety concerns), including those with previous or current substance use, prescribing ability and/or phlebotomists

Availability of advocacy groups and sources for support

Program relationship with local health officials, law enforcement, community members

(continued on next page)

Table 2 (continued)

Changes in livelihood and economic opportunity**Socio-economic status**

Job status/(un)employment
 Transportation/other resources for accessing employment and/or services
 Income level
 Influx of cash from stimulus checks
 Barriers to receiving stimulus checks
 Closures of Departments of Motor Vehicles (DMVs) and other social services
 Public solicitation (money, food) ability
 Ability to access Wi-Fi outside SSPs or other service providing organizations

Housing (in)security

Eviction
 Forced shifts in/closures of encampments
 Shifts to homelessness
 Temporary housing (hotels) for unstably housed people

MICRO-ENVIRONMENT: NETWORKS**Changes in sexual networks**

Number of partners
 Number of new partners
 Sex of partners
 Any transactional sex partners
 HIV/STI/HCV status of partners
 Substance-use among partners

Changes in substance-using networks

Number of partners
 Number of new partners
 HIV/HCV status of partners
 Syringe/equipment/substance-sharing behaviors

Changes in social networks

Peer support systems
 Substance use norms and attitudes
 Family support systems

Changes in work-related networks

Contacts with colleagues
 Time spent with colleagues
 Changes in makeup of colleagues

INDIVIDUAL CHARACTERISTICS**Changes in mental health**

Posttraumatic stress
 Depression
 Anxiety
 General stress
 Loneliness/isolation
 Worsening of pre-existing mental health conditions
 Psychiatric effects to changes in the drug used

Changes in general health (and vital) status**Chronic condition management**

HCV sustained viral response/cure
 HIV viral suppression
 Diabetes management
 Asthma and other respiratory disease management
 Other chronic conditions

COVID-related

COVID incidence
 COVID severity
 Long COVID
 COVID vaccination
 Possible immune system resilience among PWID

Mortality

All-cause mortality
 COVID-related mortality
 Cold weather-related mortality

Changes in social interactions**Social network interactions**

Social distancing, isolation
 Frequency and quality of interactions between PWID and service delivery staff
 Interactions between PWID, their families, and other support systems

Violent interactions

Domestic violence
 Gender violence
 Law enforcement violence

(continued on next page)

Table 2 (continued)

Changes in service utilization
Engagement in telemedicine and other alternative service delivery modes
Technical resource availability for telemedicine access
Correct use of pre-packaged supplies and no touch delivery methods for supplies (harm reduction, medications)
Engagement in HIV/HCV/substance use disorder prevention and treatment services
Adherence to HIV/HCV/SUD treatment medications
MEDIATORS
Changes in sexual behaviors
Intermittent abstinence
Sexual risk behavior (condomless sex, multiple casual partners)
Sex work
Drugs used during sex
Changes in substance use behaviors
Frequency of injection
Binging behaviors
Using alone versus with others
Intermittent abstinence (intentional and unintentional)
Shifts to use of different substance types
Increased fentanyl use (intentional and unintentional)
Shifts to injection from other types of administration
Alcohol and tobacco use
Polysubstance use
Shifting sources for drug procurement
HEALTH OUTCOMES OF INTEREST
HIV incidence
HCV incidence
STI incidence
Skin and soft tissue infections
Fatal and non-fatal overdose

creases in overdose mortality, federal funding could be used to purchase fentanyl test strips for rapid drug identification (Centers for Disease Control and Prevention, 2021b; Goldman et al., 2019; Peiper et al., 2019). Another is that buprenorphine was increasingly prescribed through telemedicine with allowances for take-home doses (Substance Abuse and Mental Health Services Administration, 2021; Tofighi et al., 2021). Additionally, at the policy level in many states, persons working in substance use services programs, including in harm reduction, were classified as “essential workers,” a recognition of the importance of providing services to persons who use drugs (Centers for Disease Control and Prevention, 2021c). These substantial policy changes, if maintained, may have potential to effect long-term change PWID health (Green et al., 2020).

Shifts in social determinants of health (SDOH) also exert macro-level forces on PWID health risks. For the purposes of this framework, social determinants refer to societal valuation as determined by culture and social norms, power structures and societal hierarchies (e.g., class differences). While SDOH are frequently conceptualized at multiple ecological levels in frameworks, our framework represents this concept at the macro-level only. This facilitates illustration of wide-ranging effects of social forces (e.g., structural racism) on other framework components, while also differentiating macro-level forces from more proximal SDOH factors (e.g., economic opportunity).

Two subcategories of SDOH are highlighted here: structural racism and law enforcement/incarceration, both of which exert forces on PWID health that changed during the pandemic. Structural racism and resulting social marginalization are particularly critical constructs affecting all other framework components and how individual PWID move through these components. Importantly, the ways in which PWID experience structural racism likely changed — both exacerbated and attenuated — during the racial reckoning and Black Lives Matter movement co-occurring with the pandemic. Policing practices also changed in many ways during this time, for example as law enforcement officers took on roles related to COVID-19 prevention and control such as disruption of encampments. In some states such as California, efforts were

made to de-populate prisons following the discovery of large COVID-19 outbreaks among prisoners (Ryckman et al., 2021); although many prisons remain over-crowded, which poses ongoing transmission risks (Chin et al., 2021; Strathdee et al., 2021).

Mezzo-environment

In our framework, the mezzo-environment comprises intermediary mechanisms connecting society to individuals and is characterized by community and neighborhood-level arrangements of resources, relationships, organizations, and conditions (Glass & McAtee, 2006). There are three categories of mezzo-level factors exerting influence on PWID health outcomes highlighted here: drug supply and distribution systems, the service delivery landscape, and livelihood and economic opportunity. Drug supply and distribution systems include pricing, availability, distribution channels, type, and quality of substances used. An example of a potential pandemic-related change is variation in levels of drug concentration with fentanyl and fentanyl analogues due to disruption of supply chains (Catalani et al., 2020; Di Trana et al., 2020; United Nations Office on Drugs and Crime, 2021). On the other hand, disruption in the drug supply system may have resulted in some PWID entering treatment to reduce use as well as reductions in substance use outside of treatment (Genberg et al., 2021; Janulis et al., 2021; Price et al., 2021).

The service delivery landscape includes changes in PWID health-related program offerings during the pandemic. Due to the wide range of potentially affected services, we present included factors in subcategories: HIV and HCV screening and testing; provision of treatment and/or medication for substance use, infectious disease, or other health conditions; operations and staffing for service providing organizations; and other program and service offerings including vaccination. Examples of factors exerting change in PWID health in this framework component are shifts in service delivery modes (e.g., from in-person to remote delivery), changes in opioid prescribing and dispensing practices, provision of prison/jail throughcare services, and closures or reduction in

opening hours of syringe services programs (SSP) operations. While in-person services were interrupted on many levels (Herring et al., 2021), there were also beneficial changes in the service delivery landscape. For example, due to a change in SAMHSA guidelines, some substance use treatment programs reduced or removed treatment restrictions, including for medications for opioid use disorder, permitted treatment entry through telemedicine, and reduced requirements for in-person clinic attendance (de Vargas et al., 2021; Harris et al., 2020; Levy et al., 2021; Molfenter et al., 2021; Samuels et al., 2020; Substance Abuse and Mental Health Services Administration, 2021; Tofighi et al., 2021; Wood et al., 2020). Additionally, some syringe services programs moved from a one-for-one exchange model to a “needs-based” model (Glick et al., 2020).

The final mezzo-level component, livelihood and economic opportunity, refers to fluctuations in resource access resulting from changes in global, national, and local economies during the COVID-19 pandemic (Bashir et al., 2020; Centre for Economic Policy Research, 2020). Such fluctuations may affect changes in socioeconomic status and housing security through, for example, eviction and shifts in or closures of shelters and encampments, but also through rapid influx of cash from stimulus checks. Stay-at-home orders also reduced opportunities for public panhandling. Increases in transactional sex, which in turn increased risk for COVID-19 among PWID, may have resulted from this economic instability (Strathdee et al., 2021).

Micro-environment: networks

Micro-environment refers to the composition and behavior of people most proximal to PWID, who may co-engage in risk behaviors (e.g., sexual and substance use) and may also provide important sources of social support and stabilization (Bellerose et al., 2021; De et al., 2007, 2008). Our framework includes four distinct but overlapping micro-environment networks: substance-using, sexual, work-related, and social networks.

Potential pandemic-related changes in substance-using and sexual networks include the number and turnover of people in such networks and their attributes including risk behaviors. Behavioral changes among network members may confer change in health risk outcomes among PWID, for example, through changes in infectious disease prevalence in networks (Spelman et al., 2019). Changes in social networks include composition and availability of peer and family support systems. One example of a pandemic-related shift in this framework component is relocation of PWID to family homes due to housing instability, increased economic vulnerability or changes in the retail drug market. Examples of work-related network shifts include changes in contact or time spent with colleagues who may be stabilizing intellectual and emotional influences. Two potential adverse outcomes of network-related changes are increased likelihood of PWID using drugs alone as a result of stay-at-home orders (Genberg et al., 2021; Stack et al., 2021) and reduced retention in substance use treatment due to lack of social support (Allen et al., 2021; Mallet et al., 2021).

Individual characteristics

Individual characteristics of PWID that likely changed during the pandemic and have potential effects on health outcomes are conceptualized in four categories: mental health, general health status, social interactions, and service utilization. Individual characteristics are affected by higher level factors and connect upstream determinants to behavioral mediators that directly affect changes in health risks.

Mental health is affected by components of macro- and mezzo-environments, e.g., shifts in public health resources away from PWID-related services, economic downturn and job loss, all of which may ultimately change substance-using and sexual behaviors and subsequent

risk for infectious diseases. Examples of relevant mental health factors include post-traumatic stress, depression, anxiety and general stress, as well as psychiatric effects due to changes in substances used (McKnight-Eily et al., 2021).

General health status comprises the remaining categories of illness, disease, injury, and death exerting individual-level forces on risk for health outcomes of interest. Subcategories of the general health status framework component include chronic disease management, COVID-19-related health status, and mortality. Examples of factors that may have changed during the pandemic and affect change in health outcomes include ability to achieve HCV sustained viral response, management of both chronic conditions such as diabetes and infectious diseases such as HIV, morbidity associated with long COVID-19, as well as both all-cause and COVID-19-related mortality.

Social interactions refer to the individual social experiences of PWID during the pandemic. These include positive and negative interactions and are greatly influenced by social network factors described in the micro-environment. Pandemic-related changes in social interactions may include social distancing behaviors and interactions among PWID and their families (Genberg et al., 2021; Price et al., 2021). This framework component also includes violent interactions between PWID and people in their networks and/or law enforcement.

Use of services refers to service-seeking and receipt of prevention and treatment services intended to reduce risk for health outcomes of interest. Modes of accessing those services are also included in this framework component. Relevant factors may include availability of technical resources needed to access remote services (e.g., phone, internet access) and correct use of pre-packaged supplies delivered in the context of no- and low-touch services (e.g., naloxone, medications).

As with other sections of the framework, there are important interactions between and within individual-level framework components. For example, changes in social interactions could lead to improvements or declines in mental health, and new or exacerbated mental health conditions may reduce health-seeking behaviors and subsequently affect successful management of health conditions such as HIV infection.

Mediators of framework: sexual and substance-using behaviors

Sexual and substance-using behaviors are conceptualized as the most proximal mediators of PWID health outcomes of interest: HCV, HIV, and STI incidence; overdose incidence; and skin/wound infections. These include behaviors that are influenced by all upstream framework components and provide direct opportunities for transmission of infectious diseases or drug overdose. Examples of behaviors that directly confer risk of infectious disease framework outcomes are condomless sex, multiple sex partners, transactional sex, and sex work. Behaviors that directly confer overdose risk are binge use of substances, including alcohol, shifts in substance types and combinations used, and intentional or unintentional use of fentanyl (Kral et al., 2021; Price et al., 2021).

Effect modifiers of framework

Effect modifiers of PWID health conferring differential risk or protection are those of person, place, and time. Effect modifiers are not listed individually in Table 2 but are illustrated as part of the framework in Fig. 3. Personal characteristics include demographic and personality characteristics such as age, race/ethnicity, and sex, as well as impulsivity and emotion regulation. Place characteristics include attributes tied to geo-spatial (e.g., rural, urban) and politically-defined (state, city, jurisdictional) locations. Effect modifiers of time include both short-term (daily, monthly) and longer-term periods (e.g., past, ongoing, and future pandemic eras or waves) during the pandemic. These effect modifiers affect how changes in PWID health are experienced across framework components.

Data sources for measurement

To inform operationalization of the framework, stakeholders were also asked to identify existing data sources measuring framework components, and these sources are compiled in Supplemental Table 1. Importantly, this list does not comprise results of a data landscape review and only includes data sources identified in stakeholder meetings. Sources include ongoing or previous cohort or cross-sectional research studies, surveillance systems, and administrative or service delivery datasets. We provide the full list of identified sources, with indications of which framework components are at least partially measured by each data source. Icons representing relevant effect modifiers (person, place, time) are placed alongside source name to indicate potential data stratifications by the factors. Sources are organized by whether PWID-specific information can be derived from the sample population. Finally, plus signs indicate availability of data for current PWID (e.g., people injecting within the last year).

Framework component coverage

Identified data for measuring framework components encompassed both publicly accessible and proprietary datasets. Several sources collected data across many framework components: cohort studies including the Collaborating Consortium of Cohorts Producing NIDA Opportunities (C3PNO), NHBS, and NASEN/NYU's Dave Purchase Memorial surveys.

Supplemental Table 1 suggests several gaps in data availability for various framework components. Data on substance-using, social, and sexual networks are available in very few data sources. Few sources include data on drug supply and distribution systems, particularly for substances specifically used by PWID. Notably, data on PWID could not be disaggregated from the sample or study population in many data sources. None of the data sources we identified for measuring macro- or mezzo-level economic changes contain data on PWID specifically.

Discussion

This measurement framework is the result of a collaborative, expert stakeholder-driven process and is intended to increase the quality and timeliness of research and interventions to improve the health of PWID. Diverse perspectives of participating stakeholders enabled development of a framework that fulfills our primary aims of elucidating, measuring, and intervening on multi-level factors that affect PWID health during the COVID-19 pandemic. It includes factors that influence PWID health outcomes on proximal and distal levels, including policy and resource allocation (macro-), the service delivery landscape (mezzo-), and networks (micro-), in addition to individual-level characteristics. Notably, most components added to the "skeleton" framework by stakeholders were distal, upstream factors such as changes in policies, public health resource allocation, experiences of structural racism, and the economy. We chose a framework orientation with elements of both the socio-ecological model (Bronfenbrenner, 2004) and the risk-environment model (Rhodes, 2002) to illustrate these health determinants.

Our framework is an expansion of previous frameworks on substance use, including those specific to the COVID-19 pandemic (Cowan et al., 2021; Enns et al., 2020) and illustrates the health effects of the pandemic on PWID specifically. We borrow from the systems-wide approach these models use (i.e., all ecological levels and multi-level factors) while adding a layer of conceptual granularity to graphically illustrate the complex and dynamic nature of pandemic-related changes at proximal and distal levels. Specifically, we departed from the concentric circles typical of ecological models (Bronfenbrenner, 2004) to make visual space for interacting categories of factors (e.g., micro networks, individual characteristics, and behaviors), and highlight the proximal

area (mezzo level) where we would expect many interventions and programs to focus (e.g., service provision.). Our framework is also informed by the risk-environment model (Collins et al., 2019; Rhodes, 2002), in that it conveys downstream effects of upstream mechanisms; however, an important feature of this framework is visual linearity and specification of how upstream factors on multiple levels affect PWID behavioral and health outcomes. For example, we demonstrate how policies and resource allocation confer changes to mezzo-level health services, which then affect individual outcomes. We ensured indicator language allowed for both increased and mitigated health risks and had a theoretical or evidentiary basis for being placed together. Further, while many concept or systems maps provide more granularity than our framework, we charged ourselves with providing a framework that could tell the fullest story on PWID health during COVID-19: thus, we endeavored to tell the clearest story possible while creating the most inclusive framework for the field of PWID health. This is in keeping with systems thinking movements which charge public health researchers and practitioners to balance both a widening, more complex view of issues while providing actionable outputs for immediate use across relevant fields (Hassmiller Lich et al., 2017; McGill et al., 2021).

Consistent with our primary aims, there are several potential uses for this measurement framework. First, the framework can guide analyses of existing data sources to measure factors that are proximal to PWID health outcomes (e.g., infectious disease incidence and overdose) through systematic reviews, meta-analyses, and other secondary data uses. Second, the framework can serve as the basis for a common, timely research agenda for researchers, advocates, policy makers, and service providers working in the field of PWID health and can also potentially influence strategic priorities of relevant funding agencies. Last, the framework can serve as a guide for variables that should be included in research and evaluation assessing PWID health outcomes potentially attributable to COVID-19 or, minimally, should provide context for interpretation of findings from such work.

Our framework includes several effect modifiers that should be considered in any of these potential uses. There are likely to be substantial differences in both needs for intervention and associated resources based on characteristics of person, place, and time. Two of the most salient characteristics that may affect how individuals move through this framework are PWID race/ethnicity and geographic setting. Pre-pandemic racial and ethnic disparities in health risks and outcomes have been exacerbated by the high burden of COVID-19 among structurally marginalized racial and ethnic minority populations, and these disparities are likely to affect PWID at least as severely as other populations (Centers for Disease Control and Prevention, 2020; Millett et al., 2020). In addition to geographic variation in the underlying COVID-19 pandemic, urbanicity likely determines how PWID experience pandemic-related changes in health outcomes (Ostrach et al., 2021; Vickers-Smith et al., 2020). For example, rural areas had substantially lower pre-pandemic harm reduction service coverage compared to urban areas, so further reductions in services may be especially dire. COVID-19 prevention policies, programs, and behaviors are also likely to differ greatly in rural versus urban areas, which may affect the extent to which PWID are affected by changes in social mixing patterns, for example.

While the framework has great utility for research agenda-setting and informing future research and program evaluation efforts, its ability to achieve our first aim – informing analyses of existing data sources – will be somewhat limited by data sparsity. Identifying data inputs to framework components was a secondary focus of our stakeholder-driven process, but this exercise suggested substantial information gaps. Across framework components, many identified data sources do not include information specific to PWID, which limits our ability to understand how PWID experience macro- and mezzo-level factors that affect downstream health risks. Data gaps identified here can inform future research investments to ensure more comprehensive measurement is ultimately possible across framework components.

Creative solutions and collaborations will be needed to rapidly identify and intervene on pandemic-related PWID health risks. Inter- and intra-sectoral collaborations will be critical for the success of such solutions. For example, public health agencies may consider sharing and matching programmatic data across systems, such as substance use treatment admissions and Medicaid, to explore pandemic-era use of health services among PWID. Where possible within confidentiality standards, public health data stewards may also consider working with researchers to add needed information to cohort data sets. Such data sharing may include, for example, death matches against vital statistics or locating information for participants who are lost to follow up. Last, mechanisms are needed to encourage rapid, privacy-protected data sharing from PWID-focused research studies with proprietary data. Ultimately, more robust surveillance for PWID is needed. NHBS is currently limited to urban areas and conducted every three years, and there is no ICD-10 code for IDU, limiting the use of clinical datasets for surveillance.

Next steps

Our consortium has several areas of planned follow-up to this measurement framework. First, we are using a ranking process to narrow the factors compiled here to a concise set that adequately represent framework components, can be written as measurable indicators, and are reasonably quantifiable using existing data sources. Second, we are building a publicly available web-based platform that will allow data stewards to contribute summary data toward indicator measurement. Contributed estimates will then be meta-analyzed within available stratifications, and these estimates will fill information gaps and help to facilitate timely public health response. Third, we envision a collaborative research study of the extent to which “risk-mitigating” policy, organizational and individual changes can be maintained throughout and after the COVID-19 pandemic. Fourth, we expect revisions to the framework will be needed over time, particularly as the pandemic changes (i.e., becomes endemic). Finally, while this effort was focused on experiences of PWID in the U.S., the COVID-19 pandemic affected PWID globally. Cross-national comparisons of the pandemic effects on PWID are an important area for future collaborative research.

Although we aimed to gather a diverse group of stakeholders for maximum breadth in terms of perspectives represented, there are undoubtedly groups or individuals who were not included due to time, logistical, and resource limitations. The framework would benefit, in particular, from the input of current PWID including those experiencing COVID-19 infection, persons who are socially marginalized, and additional non-academic stakeholders including those serving PWID through grassroots community organizations. We welcome additional group members and encourage researchers, practitioners, policy makers, and data stewards working in the field of PWID health to join our efforts. We have a unique opportunity to demonstrate how collaborating quickly and meaningfully across a public health field can facilitate timely intervention on adverse health outcomes associated with the pandemic and prevent further infectious disease and overdose consequences.

Conclusion

The stakeholder-driven process by which this measurement framework was developed underscores the need for more meaningful collaboration and data sharing in the field of PWID health. The process provides a model for collaboration across a research field in the context of a public health emergency. Our framework illustrates proximal and distal contributors to adverse PWID health outcomes that may have changed during the COVID-19 pandemic. This further helps to illustrate indicators of change in health outcomes that can be measured and monitored prior to availability of robust surveillance estimates. Additionally, framework components elucidate myriad intervention opportunities for practitioners across a broad range of levels and disciplines in public health.

Ethics approval

The authors declare that the work reported herein did not require ethics approval because it did not involve animal or human participation.

Declarations of Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Supplementary materials

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